



# **METHOD DEVELOPMENT AND VALIDATION FOR QUANTITATIVE ANALYSIS OF TIAGABINE HCl BY ULTRAVIOLET SPECTROPHOTOMETRY**

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## **ABSTRACT**

A simple and sensitive UV spectrophotometric method for the determination of tiagabine HCl in bulk has been developed. Beer's law is obeyed in the concentration range of 10 – 50 µg / mL of Tiagabine HCl. Spectroscopic determination was carried out at an absorption maximum of 257 nm for tiagabine HCl using double distilled water as a solvent. In UV spectroscopic method the linearity over concentration range of tiagabine HCl was 10 to 50 µg / mL with correlation coefficient 0.99845. The mean assay and recovery percentage was found to be 101.73% and 100.61%, respectively. The results of the analysis for the three methods have been validated statistically and by recovery studies. The results obtained with the proposed methods are in given limit by United States Pharmacopia.

**Key words:** Tiagabine HCl, UV Spectrophotometer, Beer's Law.

## **INTRODUCTION**

Tiagabine (Gabitril)<sup>1-3</sup> is chemically (3R) – 1 – [4, 4, - bis (3 – methyl – 2 – thienyl) – 3 – butenyl] – 3 – piperidine carboxylic acid. The exact role of tiagabine is unknown. However, it is believed that it alters chemical impulses in the brain that cause seizures. Tiagabine is used to control seizures. Tiagabine may cause drowsiness, dizziness, decreased concentration, vision problems or poor coordination.

A survey of literature revealed that very few analytical methods for this drug are available in human plasma and pharmaceutical formulations. These include different HPLC and other chromatographic methods<sup>4</sup>. But there is no evidence in the literature for estimation of this drug by UV–spectrophotometer method, which is essential for routine quality control analysis of pharmaceutical products containing tiagabine HCl as a fast, selective and economical method, so all attempts have been made to develop a simple

rapid and reproducible UV – spectrophotometer method with greater precision, accuracy for analysis of tiagabine HCl in bulk.

## EXPERIMENTAL

A double beam UV- visible spectrophotometer Shimadzu UV – 250 1 pc was used for spectroscopic determination, which is having spectral band width of 0.1 mm and variable (0.1, 0.2, 0.5, 1, 2 and 5 mm) accuracy of  $\pm 0.3$  mm with pair of 10 mm matched quartz cells.

All weights are taken on electronic balance. The solvent used for the experiment was double distilled water.

### Working standards and sample solution preparation

About 10 mg of tiagabine HCl (pure) was accurately weighed and dissolved in 30 mL of double distilled water in a 100 mL volumetric flask and diluted up to the mark with double distilled water. The final concentration of tiagabine HCl was brought to 0.1 mg / mL i. e. 100  $\mu$ g / mL.

### Assay

Aliquots of tiagabine HCl ranging from (1, 2, 3, 4 and 5 mL) i.e. 1 mL – 5 mL (1 mL = 100  $\mu$ g) were transferred into a series of 10 mL volumetric flasks. The volumes were made up to 10 mL with double distilled water. Middle standard was run for the  $\lambda_{\max}$ . Scanning results show  $\lambda_{\max}$  at 257 nm. This  $\lambda_{\max}$  is selected for the measurement of absorbances of standards. Thus, the absorbance was measured at 257.0 nm against solvent blank. (The amount of tiagabine HCl in the sample was computed from calibration curve.)

## RESULTS AND DISCUSSION

The optical characteristics<sup>5,6</sup> such as absorption maxima, Beer's law limit, correlation coefficient (r), slope (m), intercept (c) and molar absorptivity can be calculated from 4 replicate readings. To test the accuracy and reproducibility of the proposed method, recovery experiments were carried out by adding known amounts of the drug. The results are shown in Table 2. The reproducibility, repeatability and accuracy of this method were found to be good, which is evident by low standard deviation values (0.01732). The percentage recovery obtained 98.59% and 101.73%, indicates that the accuracy of the method is good. Thus, the developed method is simple, sensitive, accurate, and precise and

can be successfully applied for the routine estimation of tiagabine HCl in pharmaceutical and bulk analysis.

**Table 1. Optical characteristics and precision**

$\lambda_{\max}$	257 nm
Beer's law limits ( $\mu\text{g} / \text{mL}$ ) (C)	1 – 5
Molar absorptivity ( $\text{L mol}^{-1} \text{ cm}^{-1}$ )	30.5
Regression equation ( $Y^*$ )	
Slope (b)	0.03227
Intercept (a)	-0.03924
Correlation coefficient (r)	0.99845
% RSD **	0.433

$Y^* = bc + a$ , where c = Concentration of tiagabine HCl in  $\mu\text{g} / \text{mL}$  and Y = absorbance at respective  $\lambda_{\max}$ .

\*\* = for four measurements.

**Table 2. Evaluation of tiagabine HCl in bulk**

Sample	Labelled amount (mg)	Amount found by proposed method (mg)	% Recovery
T <sub>1</sub>	20 mg	19.72 $\pm$ 0.02	98.59%
T <sub>2</sub>	30 mg	30.45	101.53 %

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